INDEPENDENT PHARMACY COOPERATIVE
December 2013 • Volume: 101 • Issue: 1

Capitol Agenda
THE INDEPENDENT FORUM

FDA plans to submit a formal recommendation to reclassify hydrocodone combination products to Schedule II.

The Food & Drug Administration (FDA) plans to submit a formal recommendation to the Department of Health & Human Services (HHS) to reclassify hydrocodone combination products to Schedule II. This event will then begin a process that will lead to a final decision by the DEA on the appropriate classification of these products. It is likely that the DEA will move forward with the recommendation after the first of the year. Moving hydrocodone combination products to Schedule II means that prescriptions for these products cannot be faxed to a pharmacy or phoned in by the prescriber.

As of today, there has been no empirical data to show the extent of the benefits or related problems associated with a reclassification of hydrocodone combination products. IPC has provided comments to FDA regarding our concerns with the proposed rescheduling and have offered these simple alternatives that would address the majority of the abuse problem: modify physician practices and educate patients on the proper use and storage of this class of drug.

In what could have profound national consequences,

IPC joins the charge to file amicus brief targeting generic drug pricing lawsuit.

Two Minnesota-based employee health funds have accused CVS Pharmacy Inc., Walgreens Co., Wal-Mart Stores Inc. and others of illegally overcharging customers for generic drugs, instead of passing on discounts received in the acquisition of generics to consumers as required by Minnesota law.

Graphic Communications Local 1B Health & Welfare Fund "A" and the Twin Cities Bakery Drivers Health and Welfare Fund state that the pharmacies use "the lower acquisition cost of generic drugs as an opportunity to generate higher profits for themselves."

In response IPC along with NACDS, Thrifty White, NCPA, the Minnesota Chamber of Commerce and several other advocacy groups filed their collective motions to become amici of the Court. The underlying lawsuit cites the state law which requires pharmacies to pass along all savings associated with dispensing generics rather than brand name drugs, which the state appellate court upheld.

In addition to compensatory and actual damages caused by the inflated prices, the plaintiffs are seeking an injunction to force the defendants to stop a pricing model which may violate the Minnesota Consumer Fraud Act. Plaintiffs argue that a Minnesota pharmacy cannot make a greater profit on the sale of a generic prescription drug than it does on brand-name counterparts. The complaint states the defendants continue to do so. Similar cases are pending in West Virginia and Michigan.

H.R. 3204 The Drug Quality and Security Act Becomes Law:
What Lies Ahead?

On November 27, 2013, the President signed into law H.R.3204, the "Drug Quality and Security Act," empowering the FDA to regulate voluntarily registered entities in batch compounding and to develop a national track-and-trace system to secure the pharmaceutical supply chain and minimize opportunities for adulteration, diversion and counterfeiting.

The track-and-trace provisions will be implemented over a decade in two phases. We anticipate there will be little change, or disruptions for pharmacies in Phase 1 as it relates to managing prescription drug transactional data.

IPC's only concern is that the statute gives the Secretary of Health & Human Services (HHS) broad powers to implement track-and-trace requirements through "guidance".

In Phase 2, which implements 10 years from the date of enactment, the law will require unit level, or package specific track-and-trace requirements that may be more onerous and expensive, but requires: pilot studies; an impact analysis on small business; and, input from industry stakeholders before it goes into effect.

CMS Calls Out Improper Pharmacy Audit Recoupments

IPC commits to push pharmacy audit reform and pro-pharmacy legislation nationally.

Recently, the Centers for Medicare and Medicaid Services' (CMS) Call Letter to Part D providers stated that it is aware of improper recoupment of payments based upon simple record keeping errors. In many cases, clerical errors resulted in the Prescription Drug Plan (PDP) withholding payment on dispensed medications even though the patient received correct medications.

IPC commends CMS for acknowledging these egregious and abusive auditing practices, but these types of revenue-generating schemes must stop.

IPC's Government Relations Team considers pharmacy audit reform a top priority. Since 2011, IPC's efforts have established precedent-setting pharmacy audit bills in Utah, Montana and Colorado which have paved the way for key legislation in several other states.

Going forward, IPC will continue to champion efforts to introduce pro-pharmacy maximum allowable cost, mail order and preferred network legislation nationwide.

INDEPENDENT PHARMACY COOPERATIVE
1550 Columbus Street
Sun Prairie, WI 53590

Capitol Agenda
THE INDEPENDENT FORUM

Premier Issue
IPC at Work for You!

For more Government Relations info go to www.ipcrx.com.

Meet the Government Relations TEAM

Mark Kinney
Mark Kinney is the Senior Vice President of Government Relations at IPC. With more than 15 years of state and federal legislative experience, Kinney represents independent pharmacy nationwide. He has participated in numerous legislative conferences and committees and is a noted speaker for state and national pharmacy events.

Jim Driscoll
Jim Driscoll, IPC Director of State Government Relations, targets his efforts on local concerns for pharmacies including: Medicaid reimbursement, unfair audit requirements and PBM transparency. Jim helps to identify issues in individual states and provides assistance for the passage of pro-pharmacy legislation.

Brad Young
Brad Young brings extensive government affairs experience to IPC having served 11 years in the Colorado House of Representatives. Young has participated in effective lobbying efforts on issues such as Medicaid Reimbursement rates, pharmacy audits, drug substitution, drug discount cards, and many others.

INDEPENDENT PHARMACY COOPERATIVE

Email us at governmentrelations@ipcrx.com or call 800.755.1531.